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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,679	08/18/2003	Xavier Paliard	PP01612.009 (2300-1612.10	4593

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,679	PALIARD ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5,8,23-33,37-40,42,45 and 46* is/are pending in the application.

4a) Of the above claim(s) *23-33,37-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8* is/are rejected.

7)☒ Claim(s) *3-4, 45-46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-5, 8, 23-33, 37-40, 42, 45-46 are pending.

Response to Amendment

This is a response to the amendment filed on 07/12/2006. Claims 3, 4, 5, 8 and 23 have been amended. Claims 1-2, 6-7, 9-22 34-36, 41 and 43-44 have been canceled. New claims 45-46 are added. Claims 23-33, 37-40, 42 were withdrawn from the consideration. Claims 3-5, 8 and 45-46 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Ground Rejections:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (1) (WO 91/15771A1) or under 102(e) as being anticipated by Houghton et al. (2) (US patent No. 5, 683,864A).

3. The claimed invention is directed to a composition comprising HCV fusion polypeptides consisting of a core, NS3, NS4, NS5a and NS5b polypeptides and a pharmaceutically accepted excipient.

4. Houghton et al. (1) and Houghton et al. (2) teach that an immunogenic composition comprising HCV fusion polypeptides of HCV C domain (HCV core antigen) and at least one other HCV antigen selected from group consisting of NS3, NS4, NS5 and S, wherein the NS5 is located in the range of amino acid residues 2054-2464 that covers both NS5a and NS5b (See Houghton et al. (1) at page 21, lines 20-23). While Houghton et al. (1) and Houghton et al. (2) do not specifically mention "pharmaceutical acceptable excipients" the buffer used to store or

dissolve the fusion proteins in the kit is a pharmaceutically acceptable excipient (See Houghton et al. (1) at page 4, lines 24-30, lines 7-32 on page 3, lines 20-26 on page 21, page 22lines 14-29, pages 35-37 Houghton et al. (2) in lines 18-24 on column 5, claims 1-1, 16 and example 5).

5. Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35.U.S.C. 102(e)).

7. Claims 5 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Fields et al. (US patent no. 7,052,696B2).

8. The claimed invention is directed to a composition comprising HCV fusion polypeptides consisting of a core, NS3, NS4, NS5a and NS5b polypeptides and b), a pharmaceutically accepted excipient and an adjuvant.

9. Fields et al. teach an immunological composition and a method for using said composition to induce a immunological response including humoral and Cellular T lymphocyte immune response (See columns 18-19), wherein the composition comprises a mosaic polypeptides and a pharmaceutical acceptable carrier and also a physiological tolerable, or acceptable, diluent such as water, phosphate buffered saline or saline, and further typically

include an adjuvant such as incomplete Freund's adjuvant. The mosaic HCV polypeptides is expressed as a fusion proteins comprising an antigenic epitope of HCV NS3 located in the range of amino acids 1471-1573, an antigenic epitopes located in amino acid residues 1-91 (HCV core domain), amino acid residues 1789-1867 (HCV NS4), amino acid residues 1916-1948 (NS5a) and amino acid residues 2322-2423 (NS5b) (See columns 23-24 and claim 4). The locations of the nonstructural proteins are known in the art as evidenced by Clark et al. (J. Gene. Virol. 1997, Vol. 78, pp. 2397-2410, please see Fig. 1 in page 2398). Therefore, the claimed invention is anticipated by the cited references.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 5 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 45 of copending Application No. 10,612,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 45 of the copending application is directed to a composition comprising NS4, NS5, NS5a, NS5b and core antigen with some of defined amino acid sequences. However, they are considered as the species of generically claims HCV antigen polyproteins in claims 5 and 8 in the current application. Therefore, it is considered as an obvious version of the generic claim 5 of the current application.

12. An obvious-type double patenting rejection is appropriate where the conflict claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (fed. Cir. 1985).

13. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Wile claims 3-4 and 45-46 are free from the rejection, they are not in condition for allowance because they depend on the rejected claims 5 and 8.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Baoqun Li

Bao Qun Li

BAOQUN LI, MD
PATENT EXAMINER

09/14/2006